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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,570	05/23/2000	Francois Arminjon	MBHIB00-210	9141

7590

09/19/2005

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EXAMINER

CHEN, STACY BROWN

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/508,570

Applicant(s)

ARMINJON ET AL.

Examiner

Stacy B. Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21,22,24-27 and 29-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21,22,24-27 and 29-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's amendment filed July 6, 2005 is acknowledged and entered. Claims 21, 22, 24-27 and 29-44 are pending and under examination. In the previous Office action of February 7, 2005, the examiner indicated that the subject matter of claim 23 was free of the prior art of record. Applicant's amendment incorporated the subject matter of claim 23 into all of the pending claims. Upon further consideration, the subject matter is obvious over the prior art for reasons below and previously of record. Accordingly, this Office action is non-final. Any inconvenience to Applicant is regretted.

Claim Rejections - 35 USC § 103

2. Claims 21, 22, 24-27 and 29-44 are rejected under 35 U.S.C. 103(a) as obvious over Petre *et al.* (WO 93/24148 A1) in view of Arminjon *et al.* (AU 708777 or WO96/37222).

The claims are drawn to a method for preparing a stabilized multi-component vaccine. The components include diphtheria, tetanus, pertussis (toxoid and filamentous hemagglutinin), hepatitis B surface antigen (HBsAg), IPV (inactivated polio virus), a conjugate carrier molecule selected from tetanus and diphtheria toxoid and a capsular polysaccharide of HiB (*H. influenzae* type B), and an aluminum salt. Specifically, the tetanus toxoid and diphtheria toxoid are adsorbed onto the aluminum salt before being mixed with the other components, and the conjugate is prepared in a phosphate buffer solution before being mixed with the other components, and wherein IPV is mixed with the other components without being adsorbed onto the aluminum salt. Other claim limitations are of record.

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Petre teaches multicomponent vaccines for infants comprising various antigens such as diphtheria, tetanus, pertussis (toxoid and filamentous hemagglutinin), hepatitis B surface antigen (HBsAg), IPV (inactivated polio virus) and HiB (*H. influenzae* type B), (abstract, and page 4, lines 10-36). Petre teaches that the components of the combined vaccine are adsorbed to AH (aluminum hydroxide) or AP (aluminum phosphate). The following excerpt is taken from Petre, "After allowing time for complete and stable adsorption of the respective components, the different components are combined under appropriate conditions", page 9, lines 1-3 of Petre. Therefore, Petre clearly teaches adsorption prior to mixing with other components.

With particular regard to IPV (inactivated polio virus) which is not adsorbed in the instant claim 23, Petre discloses instances where only one of the components of the multivalent vaccine is adsorbed to an aluminum salt (claim 27) and the other components are not treated. Given the teachings of Petre, one of ordinary skill would have recognized that any components of the multivalent vaccine could be adsorbed, depending on the stability required/desired for each component. This is demonstrated by the fact that Petre teaches that other antigens (besides HBsAg) can be adsorbed or not adsorbed onto aluminum salt (claims 6, 7 and 27).

Petre also teaches amounts of antigens to be used in a 0.5 ml dose of a bulk vaccine, which can be optionally amended to use higher or lower quantities of the active ingredients: 10 Tg HBsAg, 25 Lf diphtheria, 10 Lf tetanus, 25 Tg of inactivated pertussis toxin, and 25 Tg filamentous hemagglutinin (FHA), (page 11-12, examples 3 and 4).

Petre differs from the claimed invention by not reciting the specific types of inactivated poliovirus antigens, types 1-3 (instant claims 33-35), although Petre does

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teach the use of inactivated poliovirus. Petre also differs from the claims invention by not reciting all of the amounts of antigenic elements of the instantly claimed vaccine (instant claims 33-35). The amounts of antigens in the claimed combined vaccine are: 30 Lf diphtheria, between 20-50 D antigen units of poliovirus type 1, between 4-10 D antigen units of poliovirus type 2, between 8-40 antigen units of poliovirus type 3, 10 Tg HiB, 5 Tg HBsAg, 20 Tmoles of phosphates, 5 Tmoles of carbonates, 0.125 ml of 50 Tmolar tris buffer, and 0.356 mg aluminum salt.

However, Arminjon teaches a stable, multi-component vaccine comprising 10 Tg of PRP-T (10 Tg of HiB conjugated to tetanus toxoid), 1 vaccinating dose of diphtheria, 1 vaccinating dose of tetanus, 15 Tmoles of phosphates or 20 Tmoles of carbonates, 0.25-0.3 mg of aluminum hydroxide, 40 U of polio antigen type I, 8 U of polio antigen type II, 32 U of polio antigen type III, 25 Tg of pertussis anatoxin, 25 Tg pertussis FHA, and 0.125 ml of 50 Tmolar tris buffer (pages 2-3, and examples 12 and 13). Arminjon discusses the immunogenic instability of HiB (also referred to as PRP) coupled to tetanus anatoxin. (Note: Tetanus anatoxin is synonymous with tetanus toxoid. PRP-T is an abbreviation for HiB coupled to tetanus toxoid). Arminjon teaches that the PRP-T should be suspended in a solution containing anions (phosphate or citrate) prior to contacting them with aluminum complexes (page 6, lines 33-40). It would have been obvious to combine the teachings of Arminjon including polio virus antigens types 1-3, the specific amounts of antigens, and the amounts of phosphates, carbonates and aluminum salt from the teachings of Arminjon, with Petre's combined vaccine that comprises the antigenic elements of the claimed invention to arrive at the claimed invention. One would have

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been motivated to incorporate the teachings of Arminjon into Petre's vaccine because both references teach multi-component vaccine comprising antigens adsorbed to aluminum salts for stability purposes. Although Petre fails to teach the poliovirus antigens types 1-3 and the specific amounts of antigens of the instant invention, one would have been motivated to incorporate the antigens from Arminjon into Petre's method because Arminjon's vaccine demonstrates that multi-component vaccines having antigens adsorbed to aluminum salts are stable and effective for immunization. One would have had a reasonable expectation of success that the antigens of Arminjon would have been successfully incorporated into Petre's vaccine because multi-component stable vaccines are known, as evidenced by Petre and Arminjon.

The Office has considered Applicant's asserted unexpected results, namely, the seroprotective level of Hib antibody that is exhibited when administered a vaccine with numerous valencies. The unexpected results are directed to a particular level of antibody titer against a particular antigen. Because the combination of the Petre and Arminjon reference has a reasonable expectation of success, one would have achieved the same results that Applicant achieved. Had Applicant established that the combined vaccine would not have worked to stimulate an immune response or induce protection, the obviousness rejection would not stand. However, Applicant has failed to establish that one would expect the combined vaccine of Petre and Arminjon to fail. Therefore, the unexpected results of Applicant's vaccine would have been achieved by one of ordinary skill in the art because it would have been obvious to combine the teachings of Petre with Arminjon.

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Conclusion

3. No claim is allowed. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Stacy B. Chen
September 15, 2005